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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,024	06/24/2003	Bradley G. Thompson	16596-001001	7648

26181 7590 11/24/2006

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,024	THOMPSON ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 09/12/06. Claim 34 has been amended. Claims 34-43 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claims 34-43 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous office action.

2. Applicants traverse the rejection and submit that the specification teaches and provides a method regarding using oncolytic viruses, for example reovirus or other virus like VSV, ONNX-015 virus and Delta24 virus, selectively replicate in particular phenotype of a neoplasm, which leads to death of these cells. Moreover, the method for identification of replicated viruses is readily achieved by standard methods well known in the art. Therefore, applicants conclude that the specification contains a written description of the invention.

3. Applicants' argument has been respectfully considered; however, it is not found persuasive to withdraw the rejection. To begin with, the previous 112 1st paragraph rejection is an enablement rejection rather than a written description rejection.

4. Applicants are further reminded that the previous office contains a detail discussion of all seven factors' analysis regarding whether undue experiment would be required for the claimed invention being enabled.

5. To further substantiate the rejection, the current office action would like to explain more why the claimed method is not enabled. While it is well known in the art that oncolytic viruses can more preferably replicate in neoplastic cells than the normal cells, which result in the specific killing of the neoplastic cells. However, the state of art also teaches that many kinds of tumors may contain more than phenotypes of oncogenes' mutations. For example, Einspahra et al. (Cancer Epidemiol. Biomarkers Prev. 2006, Vol. 15(8), pp. 1443-1450) teach that both Ki-ras and p53 gene mutations occur with sporadic colorectal adenoma (Please see 1443, 1449 and

Table 6). Moreover, one oncolytic virus can also preferably replicate in more than one phenotypes of neoplastic cells (Please see Smith et al. Exp. Opin. Invest. Drugs 2000, Vol. 9, No. 2, pp. 311-327, Table 2).

6. Although the specification explains the general mechanism of oncolysis mediated by an oncolytic virus, it does not provide any evidence regarding how to distinguish which virus kills the tumor cells if more than one kind of oncolytic viruses are administrated simultaneously in the culturing mix of neoplastic cells, especially, if the neoplastic tissues contains more than one kinds of oncogens or tumor suppressor genes mutations. The specification does not teach or give any guidance regarding how to use such kind of mixture of viruses to differentiate the phenotype of a tumor containing more than phenotypes of oncogens mutations or tumor related genes mutations. For example, oncolytic herpesvirus G207 (HSV mutated with γ34.5 gene) and adenovirus Onyx-015 (Adenovirus with E1B mutation) can permeably replicate in both ras and/or p53 mutated neoplastic cells. If both viruses are admitted into a neoplasm that has both ras and p53 mutation, both viruses will preferably replicate well in the cancer cells and lead the cancer cells death (See Smith et al. Exp. Opin. Invest. Drugs 2000, Vol. 9, No. 2, pp. 311-327). Oncolytic Reovirus can replicate well in both ras and/or ral gene mutated neoplasm as well as many kinds of cancer cells having defective interferon response pathway (See Norman et al. Proc. Natl. Acad. Sci. U S A. 2004, Vol. 101, No. 30, pp. 11099–11104). Therefore, a person skilled in the art would not be able to find which phenotype of the cancer cell is by just observing the cancel cell death after one or more onclytic viruses are administrated into a neoplasm as the rejected claims drafted.

7. Given the above further analysis of the factors cited in previous office action, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Conclusion

No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li

11/20/2006

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